REMARKS

In the Office Action, claims 5, 6, and 41 are rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the Office Action, claims 1-5, 7-14, 27-31, 33, 34, 40-46, 48, 49, 58-61, 63, and 65-68 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Number 5,203,326 to Collins.

In the Office Action, claims 1, 15, 18, 21, 24, 27-39, 44-46, 48-61, 63, and 65-69 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Number 5,531,768 to Alferness.

In the Office Action, claims 1, 6, 27, 32, 44, 47, 58, and 62 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Number 6,381,493 to Stadler et al.

In the Office Action, claims 16, 17, 19, 20, 22, 23, 25, 26, 64, and 70-73 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In response thereto, claim 1 has been cancelled and claims 2-7, 9-15, 27, 35, 36, 38-41, 43, 44, 50, 51, 53-55, 57, 70-73 have been amended. Accordingly, claims 2-73 are now pending. Following is a discussion of the patentability of each of the pending claims.

Preliminary Matter

In claim 41, line 1, the second occurrence of "the" has been replaced with --a-- in response to the rejection under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 5 and 6 have not been amended in response to the rejection under 35 U.S.C. §112, second paragraph because "intracardiac electrogram signal" is recited in claim 15, line 5 and claims 5 and 6 depend on claim 15.

Independent Claims 3, 4, and 9

Claim 3 recites a method comprising detecting myocardial ischemia based on a change in an electrogram signal, and in response to detecting myocardial ischemia, ignoring the sensor indicated rate and varying an inter-ventricular timing interval. In response to detecting myocardial ischemia, claim 4 recites ignoring the sensor indicated rate and varying an inter-atrial timing interval, and claim 9 recites switching from a single-chamber ventricular stimulation mode to a biventricular stimulation mode.

The Collins reference discloses an antiarrhythmia pacemaker that detects precursors to cardiac arrhythmia (i.e., ischemia) and initiates a therapy including autonomic nervous system stimulation and antiarrhythmia pacing therapy to directly inhibit sympathetic action and break the interaction between myocardial ischemia and sympathetic hyperactivity. Nowhere does the Collins reference disclose or suggest initiating a therapy such as varying an inter-ventricular timing interval (biventricular timing interval), varying an inter-atrial timing interval (biatrial timing interval), or switching from a single-chamber ventricular stimulation mode to a biventricular stimulation mode.

The Alferness reference discloses an atrial defibrillator that applies cardioverting electrical energy to the atria if the atria are in need of cardioversion and if an ischemia detector does not detect ischemia of the heart. Nowhere does the Alferness reference disclose or suggest initiating a therapy such as varying an inter-ventricular timing interval, varying an inter-atrial timing interval, or switching from a single-chamber ventricular stimulation mode to a biventricular stimulation mode.

The Stadler et al. reference discloses an implantable medical device that detects myocardial ischemia and triggers delivery of a therapy to alleviate or avoid exacerbating the ischemic condition. In one example, typically an upper rate limit for tracking atrial depolarizations or P-waves is programmed by the physician. If the patient suffers an ischemic episode, the upper rate limit is lowered to avoid pacing the ventricles at a rate which would exacerbate myocardial ischemia. However, nowhere does the Stadler et al. reference disclose or suggest initiating a therapy such as varying an inter-ventricular

timing interval, varying an inter-atrial timing interval, or switching from a single-chamber ventricular stimulation mode to a biventricular stimulation mode.

Accordingly, it is respectfully submitted that independent claims 3, 4, and 9 are in condition for allowance.

Independent Claim 15

Claim 15 recites a method of monitoring myocardial ischemia. The method comprises determining a sensor indicated heart rate, pacing at the sensor indicated heart rate, sensing an intracardiac electrogram signal, and detecting myocardial ischemia based on a change in the electrogram signal. In response to detecting myocardial ischemia, the sensor indicated rate is ignored and one or more pacing parameters are selectively adjusted. Sensing the cardiac electrogram signal comprises electrically coupling at least two sensing electrodes to form a single sensing electrode with an expanded surface.

In one embodiment of the present application, two electrodes located on a coronary sinus lead are coupled together to operate as a single, larger coronary sinus sensing surface. Two electrodes located on a right ventricular lead are also coupled together to operate as a single, larger right ventricular sensing surface. Thus, EGM signals may be obtained from differential signals between the coupled coronary sinus electrodes and the coupled right ventricular electrodes. According to the specification (see page 16, lines 21-29), coupling two sensing electrodes to form a single sensing electrode enables more sensitive detection of myocardial ischemia than a single sensing electrode with a smaller surface area. While the smaller sensing surface area strongly favors the detection of local potentials, shorting the electrode pair (or pairs) results in a simulated large electrode with enhanced ability to detect remote myocardial ischemia. This is important since myocardial ischemia begins in the endocardial surface, which is about 2 cm away from the coronary sinus lead (also referred to as LV lead) 24 which extends in an epicardial vein.

The Collins reference discloses a pulse module (10) and leads for connecting the pulse module to a patient's heart. The leads comprise an atrial cardiac lead (12) and a ventricular cardiac lead (13) (see Figure 1). Nowhere does the Collins reference disclose or suggest electrically coupling at least two sensing electrodes to form a single sensing electrode with an expanded surface. In the Collins reference, EGM signals are obtained from differential signals between a first single electrode and a second single electrode.

The Alferness reference discloses an implantable lead system having an intravascular lead (32) and an endocardial lead (36). The endocardial lead has a tip (38) and a ring electrode (40) adapted for placement in the right ventricle. The intravascular lead has a tip electrode (44) adapted for placement in the coronary sinus or the great cardiac vein and a ring electrode (46) adapted for placement in the superior vena cava or right atrium. The tip electrode and ring electrode of the intravascular lead are referred to as the first electrode pair for sensing R waves. The tip electrode of the intravascular lead and the tip electrode of the endocardial lead are referred to as the second electrode pair for sensing R waves. The second electrode pair may also comprise the tip electrode of the intravascular lead and the ring electrode of the endocardial lead. The dual sensing of the R waves between the first and second electrode pairs is performed for the purpose of reliably sensing the R waves.

The Alferness reference does not disclose or suggest electrically coupling at least two sensing electrodes to form a single sensing electrode with an expanded surface. In the Alferness reference, EGM signals may be obtained from differential signals 1) between the single tip electrode from the right ventricle and the single ring electrode from the right ventricle, or 2) between the single tip electrode from the coronary sinus and the single tip electrode from the right ventricle or 3) between the single tip electrode from the coronary sinus and the single ring electrode from the right ventricle. Thus, differential signals are not obtained from at least two sensing electrodes coupled to form a single sensing electrode.

In one embodiment, the Stadler et al. reference discloses an electrode system comprising three electrode pairs that are aligned with the three axes of the body. In Figure 1A, three EGM signals from three respective electrode pairs are processed in parallel. However, nowhere does the Stadler et al. reference disclose or suggest coupling at least two sensing electrodes to form a single sensing electrode with an expanded surface. In the various embodiments disclosed in Stadler et al., each of the electrodes from the electrode pairs comprise single sensing electrodes.

Accordingly, it is respectfully submitted that claim 15 is in condition for allowance.

Dependent Claims 2, 5-8, 10-14, and 16-20

Claims 2, 5-8, 10-14, and 16-20 depend from claim 15 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 21

Claim 21 recites a method of monitoring myocardial ischemia. The method comprises electrically coupling at least two sensing electrodes to form a single sensing electrode with an expanded surface, sensing an intracardiac electrogram signal using the single sensing electrode, and detecting myocardial ischemia based on a change in the electrogram signal.

For at least the same reason discussed previously with regards to claim 15, it is respectfully submitted that claim 21 is in condition for allowance.

Dependent Claims 22-26

Claims 22-26 depend from claim 21 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 27

Claim 27 recites a cardiac stimulation device that monitors myocardial ischemia. The device comprises an electrode having at least two sensing electrodes. The at least two sensing electrodes are electrically coupled to form a single sensing electrode with an expanded surface.

For at least the same reason discussed previously with regards to claim 15, it is respectfully submitted that claim 27 is in condition for allowance.

Dependent Claims 28-39

Claims 28-39 depend from claim 27 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 40

Claim 40 recites a cardiac stimulation device that monitors myocardial ischemia. The device comprises circuitry that is operative to electrically coupled at least two sensing electrodes to form a single sensing electrode with an expanded surface.

For at least the same reason discussed previously with regards to claim 15, it is respectfully submitted that claim 40 is in condition for allowance.

Dependent Claims 41-43

Claims 41-43 depend from claim 40 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 44

Claim 44 recites a cardiac stimulation device that monitors myocardial ischemia. The device comprises means for coupling at least two sensing electrodes to from a single sensing electrode with an expanded surface.

For at least the same reasons discussed previously with regards to claim 15, it is respectfully submitted that claim 44 is in condition for allowance.

Dependent Claims 45-53

Claims 45-53 depend from claim 44 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 54

Claim 54 recites a cardiac stimulation device that monitors myocardial ischemia. The device comprises means for electrically coupling at least two sensing electrodes to form a single sensing electrode with an expanded surface.

For at least the same reason discussed previously with regards to claim 15, it is respectfully submitted that claim 54 is in condition for allowance.

Dependent Claims 55-57

Claims 55-57 depend from claim 54 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 58

Claim 58 recites a method for monitoring myocardial ischemia. The method comprises varying an inter-chamber timing interval in response to detecting myocardial ischemia.

For at least the same reason discussed previously with regards to claims 3 and 4, it is respectfully submitted that claim 58 is in condition for allowance.

Dependent Claims 59-73

Claims 59-73 depend from claim 58 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

CONCLUSION

In light of the above claim amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

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